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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,378	03/04/2002	Antonito T. Panganiban	960296.98849	8085

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QUARLES & BRADY LLP  
411 E. WISCONSIN AVENUE, SUITE 2040  
MILWAUKEE, WI 53202-4497

EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/090,378

Applicant(s)

PANGANIBAN ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-6, 17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/4/2002. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election of Group I (claims 3-6) in the response filed October 21, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### ***Sequence listing***

Applicant's CRF and paper sequence listing have been entered.

#### ***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449 submitted March 4, 2002, is attached to the instant Office Action.

#### ***Claim Objections***

Claim 6 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim does not further limit the parent claim from which it depends, in claim 3 step (a) the compound to be tested is an inhibitor.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-6 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The claims do not set forth clear, distinct and positive process steps with a resolution or correlating step that clearly relates the preamble of the claim. The claims lack a measurement step or a positive process step to carry put the claimed methods, it is not clear what interaction between Vpu/Ubp will be indicative that the compound is a modulator of the interaction. The claim is indefinite in its recitation of “modulating” because it is ambiguous as the nature, direction (positive or negative) or degree of said modulating.

Claims 3-6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rendered indefinite in that they only describe the composition by an arbitrary name, Ubp which is defined as being a Vpu binding protein and as such is only described by its functional terms and the name does not provide any indication regarding the structure of the molecule. While the name itself may have some notion of activity of the protein, there is nothing in the claims which distinctly describes the protein. For example, others in the field may isolate the same protein (Ubp) and give it an entirely different name. Applicant should particularly point out and distinctly claim the “protein molecule” by claiming characteristics

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associated with the protein (e.g. activity, molecular weight, amino acid composition, N-terminal sequence, etc.). Claiming a biochemical molecule by a particular name given to the protein by the various workers in the field fails to distinctly claim what that protein is and what the composition is made of.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for testing the *in vitro* interaction between Ubp and Vpu using coprecipitation experiments or an *in vivo* assay using yeast –2 hybrid system, does not reasonably provide enablement for measuring the *in vivo* interaction between the two molecules in a virally infected cell which comprises both Vpu and Ubp. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicants have not provided a method of measuring the interaction between Vpu and Ubp using *in vivo* methodology.

Applicants have shown that the lack of Vpu expression results in a 5 fold decrease in particle release and that Ubp overexpression caused a 4 fold decrease in the viral particle release (see specification page 37, lines 9-13). However, measuring viral particle release alone would not be

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sufficient in determining whether a compound effects the interaction between Vpu and Ubp *in vivo*, the compound could have an effect much earlier in the viral life cycle by not allowing the virus to replicate or transcribe the viral genome or the putative inhibitory compound could have an effect on the viral entry into the cell which would also result in a decrease in viral particle release. Hence applicants have not provided a means for correlating and measuring the interaction between Vpu and Ubp in an *in vivo* setting as required by in the instant claims. Therefore, the instant invention is not enabled for the full scope of the method as claimed.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 3, 5 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Bour et al. (Journal of Virology 1995).

The instant invention is directed to an assay to identify modulators of the U binding protein (Ubp)/ Vpu interaction, comprising the steps of exposing Vpu and Ubp together in the presence of a candidate inhibitor. Ubp is defined by the applicant as a cellular protein that binds viral protein U (Ubp). The term “a preparation” is interpreted to mean “a composition”.

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Bour et al. discloses Vpu interacting with the cytoplasmic tail of CD4 (see Fig 1). CD4 is purified by immunoprecipitation (Fig 3 b) and Vpu is shown to interact with CD4. By definition CD4 is a composition of a U binding protein. The reference discloses that p56lck is a competitive inhibitor in that both Vpu and p56lck molecules bind the U binding protein CD4 (see page 1515, column 2). Therefore, the instant invention is anticipated by Bour et al.

### *Conclusion*

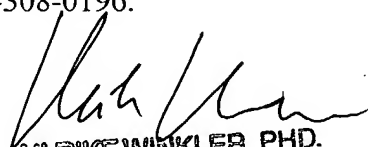
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294, please note after February 2004 the telephone number will change to 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The official fax phone number for the organization where this application or proceeding is assigned is 703-872-9306; for informal communications please use 703-746-3162, please note after February 2004 the fax phone number will change to 571-273-0912.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
ULRIKE WINKLER, PH.D.  
PATENT EXAMINER 1/26/04